

Patent Claims

1. Method for the differential-diagnostic early detection and detection, for the assessment of the severity, and for the assessment of the success of a therapeutic treatment of sepsis and severe infections, in particular sepsis-like systemic infections, characterized in that the content of at least one peptide prohormone other than procalcitonin and/or of a partial peptide derived therefrom, which is not the mature hormone obtainable from said peptide prohormone, is determined in a sample of a biological fluid of a patient, and the presence of a sepsis or sepsis-like systemic infection, its severity and/or the success of a therapeutic treatment are determined from the detected presence and/or amount of the determined peptide prohormone.

2. Method according to Claim 1, characterized in that the peptide prohormone is selected from the group consisting of pro-gastric-releasing peptide (proGRP), pro-endothelin-1 (pro-END), pro-brain-natriuretic peptide (pro-BNP), pro-atrial-natriuretic peptide (pro-ANP or pro-ANF), pro-leptin, pro-neuropeptide-Y, pro-somatostatin, pro-neuropeptide-YY or pro-adrenomedullin (pro-ADM).

3. Method according to either of Claims 1 and 2, characterized in that by the determination a partial peptide is detected which differs from the known complete peptide prohormone by the lack of a dipeptide at the amino terminus thereof, as it can be cleaved off by dipeptidyl-aminopeptidase IV (DP IV or DAP IV or CD26) from the end of a peptide.

4. Method according to Claim 3, characterized in that

the dipeptide is an Xaa-Pro dipeptide, Xaa representing the amino-terminal amino acid of the complete prohormone peptide.

5. Method according to any of Claims 1 to 4,
characterized in that said determination of said
peptide prohormone is carried out as an immunoassay
or precipitation assay, and a diagnosis of the
presence of sepsis or severe sepsis-like infections
is made if the concentration of the peptide
prohormone determined is significantly higher than
the values for the same prohormone observed in
healthy normal persons.

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15. 6. Method for the differential-diagnostic early
detection, for the detection, and for the assessment
of the severity and for the assessment of the
success of a therapeutic treatment of a sepsis and
sepsis-like systemic infections, characterized in
that the content of dipeptidyl-peptidase IV (DP IV;
dipeptidyl-aminopeptidase IV; DAP IV or CD26) is
determined in a serum or plasma sample of a patient
and the presence of a sepsis or sepsis-like systemic
infection is diagnosed on the basis of a
concentration of dipeptidyl-peptidase IV which is
significantly reduced compared with healthy normal
subjects.

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7. Procalcitonin 3-116 prepared by genetic engineering.

8. Method for the preparation of procalcitonin 3-116 by
genetic engineering, comprising
- inserting a cDNA sequence coding for the 114
30 amino acids of procalcitonin 3-116 into a
suitable vector,
- transforming suitable host cells with the vector
formed so that they express procalcitonin 3-116,

- working up said host cells,
- recovering a fraction containing the expressed
procalcitonin 3-116, and
- obtaining from said fraction said procalcitonin
5 3-116 as a product prepared by genetic
engineering in at least 90% purity by
chromatographic purification.

9. Use of recombinant procalcitonin 3-116 as a
10 calibrator in procalcitonin assays or for the
preparation of therapeutics for the prevention and
treatment of sepsis and sepsis-like systemic
infections.

10. Method for the measurement of procalcitonin 3-116 as
an indication-independent diagnostic parameter.